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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ragnar Ek

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YOUNG & THOMPSON

209 Madison Street

Suite 500

ALEXANDRIA, VA 22314

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,389	<b>Applicant(s)</b> EK, RAGNAR	
	<b>Examiner</b> Lakshmi S. Channavajjala	<b>Art Unit</b> 1611	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 14, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-18 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-17-05</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of IDS dated 10-17-09 and response to restriction requirement dated 5-14-09 is acknowledged.

1. Applicant's election with traverse of species I (claims 1-13, 15-18 and 21-24) in the reply filed on 5-14-09 is acknowledged. The traversal is on the ground(s) that at the very least, claim 14 should be examined with Species I because Claim 14 adds an additional excipient for forming an outer membrane layer to the composition of claim 1 and hence the claims do share the same technical feature i.e., the composition of claim I. Applicants argue that for the method claims 19 and 20, these claims are also directed to the inclusion of a further outer layer to a composition as recited in claim 14 (claim 19) and claim 11 (i.e., claim 20 depends from claim 17, which is directed to the composition of claim 11), and, thus, share the same technical feature: the composition of claim 1. This is not found persuasive because the cited prior art US 4,450,151 breaks the unity of invention. The cited patent describes the features of species 1 but not those of species 2 (an outer membrane layer).

The requirement is still deemed proper and is therefore made FINAL.

Therefore, claims 1-13, 15-18 and 21-24 have been considered for examination and claims 14 and 19-20 have been withdrawn as being non-elected.

### ***Claim Rejections - 35 USC § 112***

2. Claims 3, 7, 11, 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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3. Claim 3 recites preferably 3-95% without any range before the term preferably. It is unclear what the actual range is from which applicants prefer 3-95%.

4. Claim 7 recites milled qualities of microcrystalline cellulose, which is vague and indefinite. It is unclear if applicants wish to claim particulate microcrystalline cellulose. Milled qualities may include micro to microparticles, powder, granules etc.

5. It is unclear if the term suspension in parenthesis in claim 11 is part of the claim. If so, applicants are requested to delete parenthesis.

6. Instant claims 15 and 17 recite particle sizes, the units of which are not clear. It appears from the original claims and the instant disclosure that applicants wish to claim particle sizes in microns. Clarification and appropriate correction is requested.

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the

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broad recitation preferably 3-95%, and the claim also recites more preferably 10-95% which is the narrower statement of the range/limitation. Further, claim 16 recites particles have isodiametrical shape and preferably smooth texture, which is the narrower statement of the range/limitation.

8. Claim 17 recites the limitation "porous suspension comprising an active ingredient in accordance with claim 11" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 18 is dependent from claim 17.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 8-12, 16, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,450,151 ('151).

11. '151 teach an aerosol composition obtained by first preparing a suspension of hydrophobic powdered substance, alcohol and water; and further adding an intentional medicine. The composition of '151 is used for spraying on the skin and adheres to the skin (abstract). In order to prevent the clogging of agglomerates of water, alcohol and powder substance, '151 teaches addition of a gas propellant, which can be LPG or dimethyl ether, described in the examples of col. 5-10 (reads on instant claim 2).

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Examples also teach 30% water, alcohols, polymer such as starch and thus read on claim 3-5. The limitation "excipient particles after actuation can form a matrix, in- situ, on the administration site, such as the skin" in claim 8 is a future intended use and hence not given patentable weight. Besides, the composition of '151 includes the claimed features and hence is capable of forming a matrix in- situ, on the administration site, such as the skin. '151 teaches medicines such as cortisone, methylsalicylate etc., which are either soluble or suspended in the composition. The burden is on applicants to show that the compounds do not meet any of the claimed states i.e., dissolved, partially dissolved or suspended". While '151 do not teach formation of larger aggregates explicitly, the very reason to include gas propellant is to prevent clogging by aggregates. Thus, it is implicit that the powder particles of '151 form large aggregates as in claim 12. In col. 1, L 64-67, '151 teaches particles sizes of 70 to 325 mesh, where 70 mesh is about 200-500 microns and thus is within the size range of instant claim 11. With respect to claim 16, it is the position of the examiner that the particles of '151 meet the claimed features because the spray composition has powder particles that do not fly and adhere to skin uniformly. The burden is on applicants to show that particles of '151 do not have isodiametrical shape and smooth texture. For claim 22, '151 teach a skin spray. For claim 25, '151 teach cortisone that is capable of treating allergies on skin and hence treats disorders claimed. Thus, '151 anticipate instant claims.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 15, 21, 24 and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,450,151 ('151).

14. '151 do not teach the particle sizes of claim 15 and the specific limitations of applying the spray according to claims 21, 24 and 26-32. However, '151 teaches a range of particle sizes for easy application, good adhesion and excellent feeling upon skin adhesion and therefore, it would have been obvious for a skilled artisan at the time of the instant invention was made to employ optimum size of particles of the solid powder in '151 such that the ability of the composition to adhere to skin and thus impart the benefits desired are not compromised. Further, a skilled artisan would have readily been able to choose the appropriate ways of spraying the composition of '151 i.e., the height of application, area on the skin, opening of the spray pump, time of application, such that the medicament being administered is effectively administered. Additionally, instant claims do not recite any specific height, area on skin, opening diameter of the pump etc.

15. Claims 17-18 rejected under 35 U.S.C. 103(a) as being unpatentable over US 4450151 as applied to claims 1-5, 8-12, 16, 22 and 25 above, and further in view of US 6001336 to Gordon.

16. '151 fail to teach the instant wet milling or dry milling steps in the preparation of the suspension.

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17. Gordon teaches preparing dry powders comprising hydrophobic and hydrophilic components comprise combining solutions or suspensions of components and spray drying to obtain uniform powders (abstract). In col. 5, Gordon teaches suspending hydrophobic drug in an aqueous solution of a hydrophilic excipient. Gordon teaches reducing the powders to the desired particle sizes can be carried out by any of the conventional methods including wet milling, pulverization etc (col. 3, L 60-67).

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ any of the conventional techniques suggested by Gordon in preparing the spray suspension of '151 because Gordon suggests that such techniques have been employed to obtain uniform powder sizes. While Gordon suggests particle sizes of drug, '151 suggest powdered excipients and therefore a skilled artisan would have been able to employ wet milling to both active agent and excipient or either one of them depending on the particle sizes and their homogeneity.

18. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4450151 as applied to claims 1-5, 8-12, 16, 22 and 25 above, and further in view of US 6841146 to Halswanter et al ('146).

19. '151 do not teach the claimed cellulose.

20. '146 teach sprayable compositions comprising a drug, microcrystalline cellulose and carboxyalkyl cellulose (abstract). '146 teaches that the compositions when sprayed generally are not retained well at the site of the application when sprayed with pump, particularly with aqueous based sprays (col. 1) and hence causes draining of the drug to be cleared from the site. In order to be able to spray and also retain. '146 suggests



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including microcrystalline cellulose in the spray compositions. '146 also refers to the prior art (col. 1-2) where cortisone is combined with microcrystalline cellulose. It would have been obvious for a skilled artisan to include microcrystalline cellulose in the spray composition of '151 because '146 suggests that the spray composition with microcrystalline cellulose is not too viscous so as to be able to spray and at the same time viscous enough to retain on the site such that the drug is retained at least temporarily. A skilled artisan would have expected to retain the composition of '151 on skin upon application.

21. NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/  
Primary Examiner, Art Unit 1611  
August 2, 2009